REMARKS

Claims 1-13 and 15-32 are pending and are rejected. Claims 11-13 and 15 are rejected. Claims 2, 4, 5, and 7-9 were previously canceled without prejudice.

In this Amendment, claims 1-10 and 16-32 are canceled without prejudice, and claims 11 and 12 are amended; all Markush group elements but one from claim 12 are incorporated into claim 11, and therefore no new matter is introduced.

Claim Objections

Applicant has amended the claims as requested to recite the elected species and to correct the spelling error, thus addressing the objections.

Claim Rejections Under 35 U.S.C. §112

Claims 11-13 and 15 are rejected under 35 U.S.C. §112 ¶2 as indefinite.

The Examiner states that "pulmonary inflammatory process," "chronic repair process," and "clinical status" are relative terms that render the claims indefinite.

Applicant respectfully disagrees, and in support provides a Declaration under 37 C.F.R. §1.132. As stated in the Declaration, one skilled in the art would recognize the requisite hallmarks of pulmonary inflammation and chronic repair processes such that the claims are not rendered indefinite. In addition, regarding pulmonary inflammation, Applicant has disclosed, at least at p. 17 lines 6-9, that RELMα and RELMβ administration to lungs of mice resulted in the presence of perivascular and peribronchial inflammatory cell infiltrates, and also resulted in increased mucus positive cells (p. 21 line 1 to p. 22 line 21). Experimentally induced pulmonary inflammation in mice resulted in induction of approximately 500 genes in the lung. Regarding clinical status, one skilled in the art would know that it describes the patient as either having or not having some degree of pulmonary inflammatory process or a chronic repair process.

The Examiner states that claims 11-13 and 15 are indefinite because claim 11 "does not match or clearly relate back to the preamble." Applicant has amended the claims to overcome this rejection.

The Examiner states that claim 12 is indefinite "because it is not clear how the biological samples recited in the claim relate back to or further limit claim 11, from which claim 12 depends." Applicant has amended claim 11 to recite the types of pulmonary tissues recited in claim 12.

For at least these reasons, Applicant asserts claim 11-13 and 15 are sufficiently definite.

Claims 11-13 and 15 are rejected under 35 U.S.C. §112 ¶1 as not enabled.

The Examiner states that the application "does not reasonably provide enablement for a physiological assessment method comprising determining a level of resistin-like molecule α (RELMα) or resistin-like molecule β (RELMβ) in a pulmonary tissue of a patient...".

Applicant respectfully disagrees. Applicant has disclosed assessment methods for determining RELMα and RELMβ levels in lung tissue from mice with experimentally induced pulmonary inflammation. The description includes data evidencing significantly increased levels of

RELMα and RELMβ mRNA from pulmonary tissue in an animal model of asthma (at least at p. 17 line 10 to p. 18 line 13).

The Examiner states "There is little or no guidance in the specification indicating what specific pulmonary tissues are utilized in the assay . . . and which specific pulmonary diseases and pulmonary inflammatory process/ chronic repair process are to be assessed or evaluated in the patient."

Applicant has amended claim 11 to encompass the limitations in claim 12 reciting specific pulmonary tissues to be assessed for levels of RELMα or RELMβ. Further, claim 11 limits the pulmonary diseases to those involving a "pulmonary inflammatory process or chronic repair process in a patient."

Applicant disagrees that undue experimentation would be required to determine RELMβ protein expression levels in patient tissues. Protein expression is a readily determinable parameter, not requiring undue experimentation by one skilled in the art. For example, RELMβ protein levels can be determined by Western blot analysis, a well-established and common procedure, on lung samples.

For at least these reasons, Applicant asserts claim 11-13 and 15 are fully enabled.

Claims 11-13 and 15 are rejected under 35 U.S.C. §112 ¶1 as not described. Applicant respectfully disagrees.

Applicant's claims 11-13 and 15 recite a process of determining RELMα or RELMβ levels in pulmonary tissues from lungs with inflammatory diseases. Applicant has described processes for determining pulmonary levels of RELMα and RELMβ in mice with experimentally induced pulmonary inflammation, using asthma as a model of pulmonary inflammation. The description includes data, from two different allergen inductions, evidencing significantly increased RELMβ mRNA expression in asthma (at least from p. 17 line 10 to p. 18 line 13). Methods of induction, dosing, and routes of administration are provided (at least from p. 9 line 12 to p. 10 line 24). Analytical processes are described at least at p. 11 lines 1-15, p. 12 line to p. 13 line 6. Histological results are described at least in Figures 5 and 6 and at p. 21 line 1 to p. 22 line 21.

Applicant respectfully disagrees with the Examiner's characterization that

> ...the brief description in the specification of one example of a pulmonary disease (asthma) is not adequate written description of an entire genus of methods of determining the level of RELMβ to assess a patient's clinical status for a genus of pulmonary diseases and a genus of pulmonary inflammatory processes or chronic repair processes

Applicant's attached Declaration states that one skilled in the art would appreciate that, while the asthmatic lung is certainly a hallmark pulmonary disease having an inflammatory process and a chronic repair process, it is not the only such disease. Other pulmonary inflammatory diseases are contemplated and are within the scope of the claimed assessment method. As one example, cystic fibrosis is such a disease. As another example, chronic obstructive pulmonary disease (COPD) is such a disease.

Further, Applicant's claimed method assesses a parameter indicative of a pulmonary inflammatory process or chronic repair process; it is not limited to use on patients already having a diagnosis of a pulmonary disease. The described asthmatic lung model illustrates a positive response, indicating the usefulness of the assessment method. The assessment method need not be limited to use on patients with an established diagnosis of a pulmonary disease.

Claims 11-13 and 15 are rejected under 35 U.S.C. §112 ¶1 as containing new matter for "a pulmonary disease" and "a pulmonary inflammatory process." Applicant disagrees, at least because disclosure of an asthmatic lung model, described above, is recognized by one skilled in the art as is a prototypical pulmonary disease characterized by a pulmonary inflammatory process.

For at least these reasons, Applicant respectfully asserts that the rejections under 35 U.S.C. §112 are overcome and requests their withdrawal.

Claim Rejections Under 35 U.S.C. §102

Claim 11-13 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by Holcomb. Applicant respectfully disagrees at least because Holcomb does not disclose the use of RELMα or RELMβ as a physiologic assessment method to assess patient parameters indicative of pulmonary disease, as required by the applicant's claims. In addition, Holcomb does not disclose the presence of RELMβ in the lung, whereas Applicant's claims require RELMβ in a pulmonary tissue.

For at least these reasons, Applicant asserts that Holcomb does not anticipate the method claimed in claims 11-13 and 15, and respectfully requests the rejection be withdrawn.

Applicant disagrees with the Examiner's statement that Holcomb teaches, "determining the level of FIZZ1 (RELMα) mRNA and protein in bronchoalveolar lavage fluid (BALF) from mice with experimentally-induced allergic pulmonary inflammation." With respect to mRNA in BALF, Holcomb does not disclose this.

CONCLUSION

Applicant believes the Application is in condition for allowance. No fees are believed due, but if any fees are required, the Examiner has authorization to charge them to Deposit Account No. 23-3000.

The Examiner is invited to contact Applicant's undersigned representative with questions.

Respectfully submitted,

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